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LEONARD E. PRUSAK
501 GEORGE STREET
NEW BRUNSWICK, N.J. 08902

EXAMINER	
FRINKER, R.	
ART UNIT	PAPER NUMBER
332	4

DATE MAILED: 12/31/82

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-24 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 12-17 are allowed.
4. ☒ Claims 1, 2, 7-9, 11 And 18-20 are rejected.
5. ☒ Claims 3-7, 10, 11 AND 21-24 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections **MUST** be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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1. Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the recitation of "the shaft" as set forth in claim 7, line 2 is indefinite since there is no antecedent basis for a "shaft" previously recited in parent claim 3. It appears that the term "shaft" should properly read--axle- to obviate this ground of rejection.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

3. (a) the invention was known or used
by others in this country, or
patented or described in a printed
publication in this or a foreign
country, before the invention thereof
by the applicant for a patent.

4. Claims 1,2,8,9,18 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by The American Edwards Laboratories Publication. As stated in the publication in Step 4 appearing above Figure 2, "The three commissures should deflect slightly toward the center of the valve as the handle is tightened". It is apparent from Figure 4 (page 2) that the holder is made in two basic telescopic pieces in which the lower piece is an annular flange body provided with three spaced support legs that have apertures extending therethrough for receiving suture threads extended through the commissure support struts and suturing cushion. The upper piece has a flange-like body provided with slots therethrough which telescopically receive upstanding split guide posts from the lower body piece to enable guided vertical axial movement between the parts in response to the threaded attachment of the handle thereto. The jam-nut is subsequently locked in place to prevent further movement of the handle. The suture threads passing through the lower support legs are fixed in the overlying upper support legs on the upper body piece and vertical distance adjustment between the telescoping plates obviously applies tension to the

suture threads to produce the stated commissure deflection toward the center of the heart valve. The upper plate is therefore, structurally readable as applicant's claimed "thread collecting means".

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 19 is rejected under 35 U.S.C. 103 as being unpatentable over the American Edwards Lab publication in view of Carpentier et al. To use a porcine tissue valve on the bioprosthesis stent of American Edwards Lab would be an obvious expedient of selective choice since Carpentier et al (column 2, lines 55-59) teaches the use of such tissue xenografts to be conventional in the art.

7. Claims 12-17 are allowed.

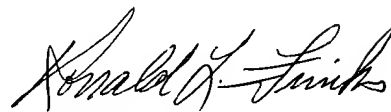
8. Claims 3-7,10,11 and 21-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, the allowability of claims 7 and 11 is contingent upon claim 7 being further amended to overcome the formal rejection under 35 U.S.C. 112. In addition, only claims 3 and 21 would be required to be rewritten in independent form since the remaining claims are dependent either directly or indirectly on claims 3 and 21.

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9. The Hancock ('823) patent is cited merely to show another resilient heart valve stent having either a natural or synthetic heart valve mounted thereon.



RONALD L. FRINKS
PRIMARY EXAMINER
ART UNIT ~~336~~ 332

R.Frinks:dg

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